

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 361

[Docket No. 2004N-0432]

**Radioactive Drugs for Certain Research Uses; Public Meeting; Reopening
of Comment Period**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until *[insert date 60 days after date of publication in the Federal Register]*, the comment period on the questions raised and issues addressed in the notice of public meeting, published in the **Federal Register** of October 5, 2004 (69 FR 59569), on the use of certain radioactive drugs for research purposes without an investigational new drug application (IND) under the conditions set forth in FDA regulations. We are taking this action in response to requests to extend the comment period and to allow additional time to review agency guidance on a related matter.

DATES: Submit written or electronic comments on the notice and/or public meeting by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: You may submit comments, identified by Docket No. 2004N-0432, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

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Certifier	L. Clawson
	DDM

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.
- E-mail: fdadockets@oc.fda.gov. Include Docket No. 2004N-0432 in the subject line of your e-mail message.
- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number for this proceeding. All comments received will be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting comments, see the "Comments" heading in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert Docket No. 2004N-0432 into the "Search" box and follow the prompts, or go to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

A transcript of the public meeting is available for review at the Division of Dockets Management and on the Internet at <http://www.fda.gov/ohrms/dockets>.

FOR FURTHER INFORMATION CONTACT: Maria R. Walsh, Center for Drug Evaluation and Research (HFD-103), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3139, FAX: 301-480-3761, e-mail: walsh@cder.fda.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of October 5, 2004 (69 FR 59569), we announced a public meeting to be held on November 16, 2004, to discuss research on radioactive drugs that is conducted under § 361.1 (21 CFR 361.1). Under § 361.1, certain radioactive drugs (drugs that exhibit spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons) are considered generally recognized as safe and effective under specified conditions of use when administered to human research subjects for certain basic research uses. These uses include studies intended to obtain basic information regarding the metabolism (including pharmacokinetics, distribution, and localization) of a radioactive drug or regarding human physiology, pathophysiology, or biochemistry, but not studies intended for immediate therapeutic, diagnostic, or similar purposes or studies intended to determine the safety and effectiveness of the drug. When conducted in accordance with § 361.1, clinical investigations of radioactive drugs are not subject to the requirements for INDs stated in 21 CFR part 312.

To facilitate discussion at the public meeting and assist us in our review of this matter, we invited comments on several questions we set forth in the **Federal Register** notice concerning the application of § 361.1. Interested persons were invited to present information at the public meeting and were given until January 16, 2005, to submit comments on the notice.

We held the public meeting on November 16, 2004. Subsequent to the public meeting, we received requests from the American College of Nuclear Physicists, the Society of Nuclear Medicine, and others that we extend the comment period on the notice on § 361.1 so that persons can consider the

issues raised in the notice and at the public meeting in light of the information in the draft guidance on exploratory INDs that we expected to issue in the near future. We published a notice of availability of that draft guidance in the **Federal Register** of April 14, 2005 (70 FR 19764).

In response to these requests, we have decided to reopen the comment period on the questions and issues stated in the October 5, 2004, notice and discussed at the November 16, 2004, public meeting. This will allow interested persons more time to review and comment on these issues in light of the information in the draft guidance on exploratory INDs.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Transcripts

You can examine a transcript of the November 16, 2004, public meeting on the Internet at <http://www.fda.gov/ohrms/dockets/default.htm> or at the Division of Dockets Management (see **ADDRESSES**), Monday through Friday between 9 a.m. and 4 p.m. You may also request a copy of the transcript from the Freedom of Information Office (HFI-35), Food and Drug Administration,

5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, at a cost of 10 cents per page or on CD at a cost of \$14.25 each.

Dated: 5/4/05
May 4, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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